

## **MEMORANDUM**

**TO:** MHCC Commissioners  
**FROM:** Bridget Glazebrook  
Health Policy Analyst, Specialized Health Care Services  
**DATE:** December 13, 2001  
**RE:** Action on Proposed Permanent Regulations  
*COMAR 10.24.15 State Health Plan for Facilities and Services:  
Specialized Health Care Services - Organ Transplant Services*

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### **Introduction**

This proposed action updates existing regulations on organ transplant services. Interested organizations and individuals were invited to submit comments on the staff draft of the State Health Plan from November 15 through December 3, 2001. The draft SHP was preceded by an issue and policy brief and an options paper.

### **Summary of Public Comments on Staff Draft**

Comments were received from two organizations (copies of the complete text are enclosed):

1. Children's National Medical Center – Beverly Farinelli, B.S.N, M.H.A, Director, Strategic Operations
2. Washington Regional Transplant Consortium (WRTC) – Lori E. Brigham, Executive Director

*Planning Regions.* Both commenters supported the staff recommendation to retain the OPO-designated service areas as regional service areas.

*Certification and Accreditation.* WRTC, the Organ Procurement Organization (OPO) for the Washington metropolitan area, supported continuing to require that transplant programs in Maryland comply with United Network for Organ Sharing (UNOS) policies and procedures.

*Compliance with Amoss Act and 42 CFR Part 482.* WRTC recommended the following additional policies to assist in increasing the number of organs and tissues available for transplantation:

- That new hospitals be permitted to offer transplant services only if they have demonstrated full compliance with all obligations imposed upon the hospital under both the Amoss Act and the 42 CFR Part 482.
- That under the section of the draft Plan entitled C. Standards. (1) Policies Applicable to Existing Providers; that a policy be added requiring that each Maryland organ transplant program should demonstrate full compliance with all obligations imposed upon hospital under both the Amoss Act and the 42 CFR Part 482.

### **Staff Response and Recommended Action**

*Determination and Enforcement of Compliance.* As noted by WRTC, State and Federal laws are in place to promote an increase in the number of organs and tissues available for transplantation. The William T. Amoss Organ and Tissue Donation Act (the Amoss Act), passed by the Maryland General Assembly in 1998, requires:

- all acute care hospitals in Maryland to report all deaths to a recovery agency;
- the Secretary of Health and Mental Hygiene to publish guidelines covering implementation of the Amoss Act;
- the Department of Health and Mental Hygiene (DHMH) to conduct death record reviews to determine compliance, where DHMH may delegate its duty to conduct the reviews to the appropriate recovery agency; and
- the Secretary to annually report to the General Assembly the results of the reviews.

DHMH has entered into an agreement with the federally designated OPOs to ensure monitoring reports of hospitals' performance.

As a condition of participating in Medicare, Federal regulations require that hospitals have and implement written protocols regarding organ procurement responsibilities, including:

- an agreement with an OPO under which it must notify the OPO, or its designee, of individuals whose death is imminent or who have died in the hospital; and
- an assurance that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues and reviewing death records.

Utilizing the State Health Plan and the CON program as a means to enforce the Amoss Act and 42 CFR Part 482 will have limited effectiveness due to the small number of hospitals expected to apply for new organ transplant services. Therefore, staff recommends that no changes be made in the Plan policies to require additional monitoring and enforcement.

*Technical Changes.* Staff proposes the following technical amendments to the draft SHP:

- Effective December 7, 2001, the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) changed its name to the Foundation for the Accreditation of Cellular Therapy (FACT). This change is a reflection of the rapidly evolving field of cellular therapy and the expansion of treatment options available since FAHCT's inception in 1994. All references to FAHCT have been updated to FACT.
- The minimum volume standards in regard to stem cell/bone marrow transplants have been clarified, based on interpretative guidance from FACT.

*"Consistent with FACT Standards and interpretative guidelines, one bone marrow transplant procedure (autologous or allogeneic) may be counted when a patient has experienced the complete sequence of pre-transplant work-up and evaluation, stem cell collection, conditioning and chemotherapy, infusion and engraftment."*

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Staff recommends that the Commission take action at its meeting on December 20, 2001, to adopt the draft SHP, with the above technical changes, as proposed permanent regulations.

## **Written Comments Received**

### ***Draft COMAR 10.24.15 State Health Plan for Facilities and Services: Specialized Health Care Services - Organ Transplant Services***

1. Children's National Medical Center – Beverly Farinelli, B.S.N, M.H.A, Director, Strategic Operations
2. Washington Regional Transplant Consortium – Lori E. Brigham, Executive Director